

## **REMARKS**

### **FORMAL MATTERS:**

Claims 1-13 and 19-26 are pending after entry of the amendments set forth herein.

Claims 1 and 19 have been amended to more particularly point out and distinctly claim the invention. These amendments are supported throughout the specification with specific support noted under the subheading "INDICATIONS" on page 15 and specifically in paragraph [0069].

New claims 20-23 are supported in the original application at page 18, paragraph [0081], line 1.

New claims 24-26 are supported within originally pending now canceled claims 14-18 and in the specification under the subheading "KITS" beginning on page 23 and specifically in paragraph [00100]. No new matter has been added.

Applicants note that art cited during the prosecution of this application was cited in support of rejections indicating that the properties of the various compounds and formulations would not be stripped away simply because the prior art did not mention these properties. While this is true applicants have now specifically added the step in claims 1 and 19 of diagnosing a human male patient has having erectile dysfunction. Clearly, such a step is not an inherent property of any compound disclosed within the cited references.

Further, independent claims 1 and 19 have now been amended to specifically indicate that the amount of drug delivered is an amount sufficient to treat erectile dysfunction in a human male patient. The cited art does not disclose treating erectile dysfunction with an aerosolized formulation and as such methods taught within the prior art would not inherently teach toward providing sufficient amounts of the drug into the patient's circulatory system in order to treat erectile dysfunction in a human male patient.

Previously cited art discloses treating pulmonary hypertension. Pulmonary hypertension is a disease of the lung. A method which treats pulmonary hypertension, in order to be effective, must have activity locally at the lung being treated. Pulmonary hypertension would not be effectively treated if the drug is rapidly absorbed into the systemic circulation. Applicants specifically claim depositing the drug on lung tissue so that it enters into the patient's circulatory system. If significant amounts of the drug quickly enter into the circulatory system then a disease of the lungs such as pulmonary hypertension would not be treated. In order to treat pulmonary hypertension the formulation and methodology would be designed to increase the residence time of the drug in the lung. This would generally be done by

targeting bronchial airways, encapsulation of the drug, or targeting ligands on the surface of the lung to which the drug would bind. These methods would keep the drug in the lung and treat pulmonary hypertension and reduce movement of the drug into the circulatory system which is needed to treat erectile dysfunction.

Based on the above it can be understood that a method which would effectively deliver the drug to the lung to treat lung disease such as pulmonary hypertension would not be desirable in terms of directing substantial amounts of the drug into the patient's circulatory system in order to treat erectile dysfunction. Accordingly, simply combining references which indicate that one drug might treat erectile dysfunction with another reference which teaches using such a drug in the treatment of pulmonary hypertension does not result in applicant's invention. When treating pulmonary hypertension or other diseases of the lung it is desirable to increase the residence time of the drug in the lung. However, when treating erectile dysfunction via inhalation it is desirable to get as much of the drug as possible away from the lung and into the patient's circulatory system quickly so that the drug can reach its desired end point and treat the erectile dysfunction. Thus, to those skilled in the art, a reference teaching toward the treatment of pulmonary hypertension is teaching away from the treatment of erectile dysfunction -- one teaches local delivery and retention of the drug locally and the other requires systemic delivery. In view of such reconsideration of the prior rejections and allowance of the application is respectfully requested.

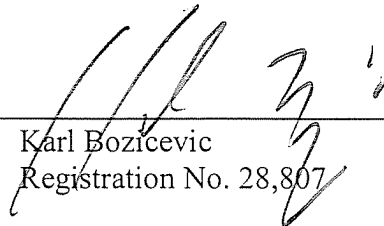
#### **CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number AERX-080CIP2.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: 7/11/06

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